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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/604,400

07/17/2003

Eric T. KOOL

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HOWREY LLP-HN

C/O IP DOCKETING DEPARTMENT

2941 FAIRVIEW PARK DRIVE, SUITE 200

FALLS CHURCH, VA 22042-7195

EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/604,400	<b>Applicant(s)</b> KOOL, ERIC T.	
	<b>Examiner</b> TERESA E. STRZELECKA	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-14,16-27 and 29-52 is/are pending in the application.  
4a) Of the above claim(s) 16-27 and 29-39 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 40-49 is/are allowed.
- 6) ☒ Claim(s) 1,5-14 and 50-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This office action is in response to an amendment filed May 21, 2009. Claims 1-14, 16-27 and 29-50 were pending, with claims 16-27 and 29-39 withdrawn from consideration. Applicants amended claims 1, 17, 18, 21, 22, 25 and 38, cancelled claims 2-4 and added new claims 51 and 52. Claims 1, 5-14 and 40-52 will be examined.

2. Applicants' amendments overcame all of the previously presented rejections. This office action contains new grounds for rejection, therefore it is made non-final.

#### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 5-14 and 50-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Art Unit: 1637

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named dabsyl group, a dimapdabsyl group, a p-dimethylaniline-sulfonyl group, a tetramethyl-phenylenediamine-sulfonyl group, a nitro benzenesulfonyl group, a dinitrobenzene-sulfonyl group (for which structures are provided in Figures 2 and 3). Thus, applicant had express possession of six particular groups in a genus which comprises hundreds of millions of different possibilities.

Specifically, the claims are drawn to a composition comprising a fluorophore compound comprising fluorescence quenching leaving group, where the fluorescence quenching leaving group is a dabsyl group, a dimapdabsyl group, an azobenzene-sulfonyl group, an amino benzenesulfonyl group, a dialkylamino benzenesulfonyl group, a p-dimethylaniline-sulfonyl leaving group, a tetramethyl-phenylenediamine-sulfonyl leaving group, a nitro benzenesulfonyl group, a dinitrobenzene-sulfonyl leaving group, a fluoro benzenesulfonyl group, a cyano benzenesulfonyl group, an arenesulfonyl group, an arylazo-substituted dabsyl group, or a gold particle conjugated to a sulfonyl group, wherein said fluorescence quenching leaving group contains a sulfur atom bonded to three oxygen atoms and a carbon chain. Aside from the structures of the six particular groups presented in Fig. 2 and 3, Applicants did not provide any structures of any other compounds comprising these groups, and no structures of groups not shown in the figures, such as an azobenzene-sulfonyl group, an amino benzenesulfonyl group, a dialkylamino benzenesulfonyl group, a fluoro benzenesulfonyl group, a cyano benzenesulfonyl group, an arenesulfonyl group, an arylazo-substituted dabsyl group, or any groups comprising these groups. Finally, Applicants did

Art Unit: 1637

not show that any of the claimed groups other than the dabsyl group possess fluorescence quenching properties.

In Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any groups other than the one depicted in Figures 2 and 3. Therefore, the claims fail to meet the written description requirement by encompassing chemical groups which are not described in the specification.

Finally, as stated in In re Ruschig, Aumuller, Korger, Wagner, Scholz, and Bander, 154 USPQ 118 (C.C.P.A. 1967):

"It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one's way through the woods where the trails have disappeared- or have not yet been made, which is more like the case here-to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none." (page 123).

In other words, Applicants have provided structures of six groups which can potentially be used as leaving groups, but have not provided any direction or guidance as to structures of any other groups comprising these groups, or ways of obtaining such groups.

5. No references were found teaching or suggesting claims 1, 5-14 and 50-52, but they are rejected for other reasons. Claims 40-49 are allowed.

Art Unit: 1637

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka  
Primary Examiner  
Art Unit 1637

/Teresa E Strzelecka/  
Primary Examiner, Art Unit 1637  
July 31, 2009